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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,349

07/23/2004

Ali Rezai

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EXAMINER

DIETRICH, JOSEPH M

ART UNIT

PAPER NUMBER

3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/502,349	Applicant(s) REZAI ET AL.	
	Examiner Joseph M. Dietrich	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-20, 23-37 and 41-52 is/are pending in the application.
- 4a) Of the above claim(s) 37 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-20, 23-36 and 42-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2010 has been entered.

Response to Arguments

2. Applicant's arguments filed February 23, 2010 have been fully considered but they are not persuasive.

In response to applicant's argument that John fails to teach exposing the patient to a painful sensation, examiner disagrees. In column 9, lines 4 – 15, John teaches a patient's pain threshold may be measured during a period of subjective assessment. It is apparent that during a period of subjective assessment, during which pain threshold is measured at different instances, that the patient would necessarily be exposed to a series of painful sensations corresponding to the times the patient provides subjective ratings of pain. In the alternative, see the rejection over John in view of Law et al. and Baudino et al.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 7-36, and 43-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 19, and 43 – 52 recite exposing the patient to first and second painful sensations. While the specification does teach on page 11, lines 20 – 26 that a patient's threshold could be measured during tactile stimulation or exposure to noxious stimuli in addition to measuring the patient's threshold to increases or decreases in temperature, the specification fails to teach exposing the patient to a "painful sensation" in addition to the other limitations of the claims. The noxious and tactile stimulations and the increase or decrease in temperature may be noticed by the patient, but aren't necessarily "painful sensations." Thus, the claims constitute new matter. Furthermore while measuring the patient's threshold for pain, it could be discovered that the patient feels no pain related to the stimulation. Then there would not be a "painful sensation."

Claims 1 and 19 recite "exposing the patient to a first painful sensation; measuring the patient's threshold for pain during the first painful sensation; ... exposing the patient to a second painful sensation; re-measuring the patient's threshold for pain

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during the second painful stimulation.” While the specification teaches on page 11, lines 20 – 24 that a patient’s threshold to pain could be measured during stimulation of the pain circuitry target site, the specification fails to teach exposing the patient to a first painful sensation prior to measuring the patient’s threshold for pain in addition to the other limitations of the claim. Page 11 states that a patient’s threshold to pain could be measured prior to stimulation of the pain circuitry target site and then the patient’s threshold to pain could be measured during stimulation of the pain circuitry target site. Thus, the claims constitute new matter.

5. **Claims 4-5, 7-18, and 20-36** are also rejected since they depend from rejected base claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 5, 7 – 20, 23 – 36, and 43 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (USPN 6,066,163) in view of Baudino et al. (USPN 6,353,762).

Regarding **claims 1, 4, 19, 20, 22, 24, and 36**, John discloses a method of affecting chronic pain in a patient, comprising: implanting a stimulator in a target site of the brain (e.g. column 3, lines 22 – 25); exposing the patient to a first painful sensation, measuring the patient's threshold for pain during the first sensation, exposing the patient to a second painful sensation, re-measuring the patient's threshold for pain during the second sensation, and adjusting the stimulation signal if necessary in response to the re-measurement of the patient's threshold for pain (e.g. Fig. 2, column 6, lines 12 – 44, and column 9, lines 10 – 15), but fails to teach that the target site is selected from the group consisting of the claimed brain locations. Baudino teaches it is known to affect chronic pain by implanting a stimulator in a target site of the brain (e.g. column 9, lines 61 – 66) wherein the target site is the anterior limb of the internal capsule (e.g. column 9, line 66), the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral hypothalamus (e.g. column 10, line 3), and/or the ventral pallidum (e.g. column 9, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation sites as taught by John with the claimed stimulation sites as taught by Baudino, since such a modification would provide the

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predictable results of optimizing the therapy to quickly and efficiently affect the chronic pain.

Regarding **claims 2, 3, 5, 7 - 18, 21, 23, and 25 - 35**, John in view of Baudino discloses the claimed invention, but fails to expressly teach that the target area is selected from the groups consisting of: the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medial frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, and the tectum. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cortical stimulation and the deep brain stimulation as disclosed by John in view of Baudino with the stimulation of the identified cortical or deep brain sites, because Applicant has not disclosed that the stimulation of the claimed sites provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stimulation of the anterior limb of the internal capsule or the anterior nucleus of the thalamus as taught by John in view of Baudino, because it provides the predictable results of effective stimulation to affect chronic pain.

Therefore, it would have been an obvious matter of design choice to modify John in view of Baudino to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cortical and deep brain stimulation methods as taught by John in view of Baudino and try different cortical and/or deep brain stimulation sites, such as the stimulation of the claimed sites, since it was known

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in the art that cortical and deep brain stimulation systems and methods use stimulation of the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medial frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, or the tectum and since it would be obvious to one having ordinary skill in the art to try different cortical or deep brain stimulation sites to provide the predictable results of determining the correct cortical or deep brain region to stimulate to affect chronic pain since different brainstem stimulation sites provide activation of selective nerves and different body regions having different functions and would allow the physician to choose the most effective site to modulate body function.

Regarding **claims 43 – 46**, John discloses wherein the first and the second stimulus are the same (e.g. 66 in Fig. 2) and where they are different (e.g. 68 in Fig. 2).

Regarding **claims 47 and 50**, John discloses a tactile stimulus (e.g. column 5, lines 15 – 20).

Regarding **claims 48 and 51**, John discloses a noxious stimulus (e.g. 68 in Fig. 2; any stimulation that would require the therapy to be changed would indicate a negative outcome and, thus, be a noxious stimulus).

Regarding **claims 49 and 52**, John discloses an increase or decrease in temperature (e.g. column 13, lines 52 – 55). Because temperature is measured during stimulation, it is apparent that the stimulation causes an increase or decrease in temperature. In the alternative, it is well known to stimulate a target site by increasing or decreasing the temperature. It would have been obvious to one having ordinary skill

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in the art at the time the invention was made to modify the stimulation as taught by John in view of Baudino with an increase or decrease in temperature as is known in the art, since such a modification would provide the predictable results of optimizing the therapy to quickly and efficiently affect the chronic pain.

9. Claims 1 – 5, 7 – 20, 23 – 36, and 43 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over John in view of Law et al. (USPN 5,938,690) and Baudino et al.

Regarding **claims 1 – 5, 7 – 20, 23 – 36, and 43 – 52**, John discloses the claimed invention as described above except for exposing the patient to first and second painful sensations and teaching that the target site is selected from the group consisting of the claimed brain locations. Law teaches it is known expose a patient to painful sensations and measure the patient's threshold for pain during the sensations (e.g. column 8, lines 35 – 62 and column 12, lines 15 – 29). Baudino teaches it is known to affect chronic pain by implanting a stimulator in a target site of the brain (e.g. column 9, lines 61 – 66) wherein the target site is the anterior limb of the internal capsule (e.g. column 9, line 66), the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral hypothalamus (e.g. column 10, line 3), and/or the ventral pallidum (e.g. column 9, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the measurement of the patient's pain threshold and using the stimulation sites as taught by John with exposing a patient to a painful sensation prior to measurement of pain threshold as taught by Law and using the

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claimed stimulation sites as taught by Baudino, since such a modification would provide the predictable results of optimizing the therapy by determining the optimal stimulation parameters and target location to quickly and efficiently affect the chronic pain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766

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